REMARKS

This Response is submitted in reply to the final Office Action mailed on November 24, 2010. The Office Action provided a three-month shortened statutory period in which to respond, ending on February 24, 2011. Accordingly, this amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1-4, 6-14 and 16-28 are currently pending. Claims 6, 12 and 18-22 were previously withdrawn. Claims 5, 15 and 29 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-4, 7-11, 13, 14, 16, 17 and 23-28 are rejected under 35 U.S.C. §103. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application. For the reasons set forth below, Applicant respectfully traverses the rejections and submits that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 1-4, 7-11, 13, 14, 16, 17 and 23-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,077,828 to Abbruzzese, et al. ("*Abbruzzese*") as evidenced by U.S. Patent No. 4,112,123 Roberts ("*Roberts*") in view of U.S. Patent No. 6,420,342 to Hageman et al. ("*Hageman*"), U.S. Patent No. 6,953,679 to Salvati, et al. ("*Salvati*"), and U.S. Patent No. 6,203,820 to Vickery ("*Vickery*"). Claims 1-4, 7-11, 13, 14, 16, 17 and 23-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Abbruzzese* as evidence by *Roberts* in view of U.S. Publication No. 2003/0119888 to Allen et al. ("*Allen*") and Sports Supplement Review, 1997, pp. 66-70 to Phillips Bill ("*Phillips*") and *Vickery*. Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Independent Claims 1-3, 17, 23-25 and 28 recite, in part, compositions having leucine, valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, and at least one essential amino acid selected from the group consisting of isoleucine, lysine, methionine, phenylalanine, threonine, tryptophan, histidine, and combinations thereof in free and/or salt form, wherein said leucine, in free and/or salt form. Applicant has found that

when dietary intake is limited below the optimal level for physiological or patho-physiological reasons, a dietary supplement must be more effective than normal food intake in order to provide a benefit. This is because in this circumstance, when a dietary supplement is given, normal food intake is likely to be reduced by a calorically equivalent amount. Consequently, a supplement designed to limit cancer cachexia, for example, should stimulate muscle protein synthesis to a greater extent than normal food intake and should not interfere with the response to meal intake. Trials of conventional nutritional supplements in patients with cancer cachexia have failed to show appreciable benefit in terms of weight gain or quality of life. Accordingly, there is a need for effective nutritional approaches capable of treating, preventing or ameliorating the effects of tumor-induced weight loss due to, for example, cancer cachexia and/or anorexia.

Applicant has surprisingly found that a formulation containing free essential amino acids as compared to a formulation containing free essential and non-essential amino acids or intact protein alone is optimal. See specification, Examples 1-2. Applicant has also found that nutritional compositions comprising a mixture of essential amino acids in free form and/or in salt form that has particularly high amounts of leucine had a stimulatory effect on muscle protein synthesis. See specification, Example 3.

In addition, Applicant has surprisingly and unexpectedly found that particularly useful compositions for promotion of muscle protein synthesis or controlling tumor-induced weight loss, such as cachexia, e.g. cancer cachexia, may be obtained by combining essential amino acids in free form and/or in salt form with intact protein. See specification, Example 2. The effect of such a combination is greater than the effect that can be achieved with either type of combination partner alone. In contrast, Applicant respectfully submits that the cited references fail to disclose or suggest every element of the present claims.

Abbruzzese, *Roberts*, *Hageman*, *Salvati*, *Allen*, *Phillips* and *Vickery* all fail to disclose or suggest compositions having leucine, valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, and at least one essential amino acid selected from the histidine, and combinations thereof in free and/or salt form, wherein said leucine, in free and/or salt form as required, in part, by currently amended independent Claims 1-3, 17, 23-25 and 28. Instead, *Abbruzzese* is directed to methods and nutritional compositions for preventing and treating cachexia and anorexia. The compositions of *Abbruzzese* include effective amounts of

(1) ω3 fatty acids, such as α-linolenic acid, stearidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid or mixtures thereof; (2) branched-chain amino acids, such as valine, leucine, isoleucine or mixtures thereof; with or without reduced levels of tryptophan and 5-hydroxytryptophan; and (3) an anti-oxidant system selected from the group consisting of beta-carotene, vitamin C, vitamin E, selenium, or mixtures thereof. See, e.g., *Abbruzzese*, column 3, lines 15-56. However, at no place in the disclosure does *Abbruzzese* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims. Indeed, at best, *Abbruzzese* discloses only 5.9% valine. See, *Abbruzzese*, Table 4.

Hageman generally describes a nutritional, pharmaceutical or dietetic preparation that includes effective amounts of ribose and folic acid, optionally combined with other components, such as niacin, histidine, glutamine, orotate, vitamin B6 and other components. See *Hageman*, column 5, lines 8-52. *Hageman* also discloses products having the following mixture of amino acids as beneficial for muscle growth when consumed in an amount of more than 2 and preferably more than 4 g per daily dose: 3-10 wt % histidine, 5-15 wt % isoleucine, 10-23 wt % leucine, 10-23 wt % lysine, 5-15 wt % methionine, 5-15 wt % phenylalanine, 5-15 wt % threonine. See, *Hageman*, column 6, line 62-column 7, line 1. At no place in the disclosure does *Hageman* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims. Indeed, at best, *Hageman* discloses only 3.5% valine. See, *Hageman*, Example 2.

Salvati generally describes fused cyclic compounds and methods of using such compounds in the treatment of nuclear hormone receptor-associated diseases such as cancer and immune disorders and pharmaceutical compositions containing such compounds. See *Salvati*, Abstract. At no place in the disclosure does *Salvati* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Roberts is entirely directed to a balanced food composition for oral ingestion and producing low residues and diminished stoolings. See, *Roberts*, Abstract. *Roberts* is cited by the Patent Office for the disclosure of the amounts of amino acids in whey proteins. At no place in the disclosure does *Roberts* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Allen is entirely directed to a composition for stimulating muscle growth having an effective amount of L-arginine. See, *Allen*, Abstract. As shown by Example 1 of *Allen*, a preferred composition of the invention included about 0.57% leucine. At no place in the disclosure does *Allen* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Phillips is cited solely for the teaching that beta-hydroxy beta-methylbutyrate (HMB) is a metabolite of leucine and may help to build muscle. See, Office Action, page 36, lines 4-8. At no place in the disclosure does *Phillips* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Vickery is entirely directed toward compositions for enhancing protein anabolism and detoxification comprising molybdenum and at least two amino acids. See, *Vickery*, Abstract. Although *Vickery* discloses valine as a potential amino acid, at no place in the disclosure does *Vickery* disclose or suggest compositions containing 8% to about 10% of valine as required, in part, by the present claims.

The Patent Office asserts that "*Vickery* teaches that L-valine aids in wound healing, muscle growth and liver diseases. L-valine is present in the composition in an amount of from about 7% to about 10% by weight, from about 8% to about 9% by weight." See, Office Action, page 23, lines 16-18. Applicant respectfully submits that *Vickery* still fails to disclose or suggest the presently claimed amounts of valine. For example, the present claims expressly require that the valine is present in an amount from about 8% to about 10% by weight of total amino acids.

In contrast, *Vickery* expressly discloses that valine may be present in amounts of about 7% to about 10% "based on the total weight of the composition." See, *Vickery*, column 2, lines 8-25. *Vickery* also expressly states that L-Valine may be present in amounts from 7% to about 10%, more preferably about 8% to about 9% "based on the total weight of the active ingredients in the composition." *Vickery* further defines the "active ingredients" as including various amino acids, molybdenum, creatinine, creatine, monohydrate, sulfur, methylsulfonylmethane, powdered egg white or powdered milk, and powdered enzymes. See, *Vickery*, column 5, lines 58-67. As such, it is clear that the "active ingredients" of *Vickery* include minerals, powdered dairy components and enzymes, among other ingredients. Thus, the amounts of valine disclosed in

Vickery are not based on the weight of total amino acids, as is required, in part, by the present claims.

For at least these reasons, Applicant respectfully submits that the obviousness rejections are improper and that the cited references fail to disclose or suggest each and every element of the present claim.

Accordingly, Applicant respectfully requests that the obviousness rejections of Claims 1-4, 7-11, 13-14, 16, 17 and 23-28 under 35 U.S.C. §103 be reconsidered and withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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